

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVOZYMES A/S,

Plaintiff,

v.

GENENCOR INTERNATIONAL, INC. and
ENZYME DEVELOPMENT CORPORATION,

Defendants.

C.A. No. 05-160-KAJ

**ENZYME DEVELOPMENT CORPORATION'S ANSWER
AND AFFIRMATIVE DEFENSES**

Defendant Enzyme Development Corporation ("EDC"), by its attorneys, responds to Plaintiff Novozymes A/S's ("Novozymes") Complaint for Patent Infringement ("Complaint") as follows:

ANSWER

1. EDC admits that the Complaint purports to set forth a patent infringement action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, that this Court has subject matter jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 and 1338, and that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

2. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint.

3. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint.

4. EDC admits the allegations of paragraph 4 of the Complaint.

5. EDC admits that the public record appears to reflect that Novozymes is the owner by assignment of United States Patent No. 6,867,031 (“the ‘031 patent”), that the patent is entitled “Amylase Variants,” and that the ‘031 patent issued on March 15, 2005, but denies the remaining allegations of paragraph 5 of the Complaint.

6. EDC admits that Novozymes contends that the ‘031 patent claims alpha amylases modified by the deletion of the amino acids at positions equivalent to positions 179 and 180, but denies that Novozymes’ statements in paragraph 6 of the Complaint completely or accurately describe all limitations of any or all claims of the ‘031 patent.

7. EDC admits the allegations of paragraph 7 of the Complaint.

8. EDC admits the allegations of paragraph 8 of the Complaint, except that EDC denies it is the sole means of U.S. sales of Genencor’s Spezyme® Ethyl.

9. EDC admits that Novozymes contends that Spezyme® Ethyl is an alpha-amylase that differs from a parent *Bacillus (Geobacillus) stearothermophilus* alpha-amylase by the deletion of two amino acids at positions equivalent to positions 179 and 180 but denies that Novozymes’ statements in paragraph 6 of the Complaint completely or accurately describe Spezyme® Ethyl.

10. EDC denies the allegations of paragraph 10 of the Complaint.

11. EDC is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Complaint.

12. EDC denies the allegations of paragraph 12 of the Complaint.

13. EDC denies the allegations of paragraph 13 of the Complaint.

14. EDC denies all other allegations of the Complaint, including in the prayer for relief, that were not expressly admitted above, including those allegations to which EDC is without knowledge or information sufficient to form beliefs as to the truth thereof.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

15. On information and belief, the '031 patent is invalid for failing to satisfy one or more of the conditions of patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND AFFIRMATIVE DEFENSE

16. EDC has not infringed any valid or enforceable claim of the '031 patent.

THIRD AFFIRMATIVE DEFENSE

17. To establish the patentability of the claims that issued as claims 1-5 of the '031 patent over prior art cited by the Examiner during the prosecution, Novozymes presented evidence that the claimed invention allegedly provided surprising and unexpected results over the prior art that warranted issuance of a patent. Specifically, Jason Garbell, Novozymes' in-house patent attorney, submitted an Amendment under 37 C.F.R. 1.111 ("Amendment") to the Patent and Trademark Office ("PTO") on September 7, 2004 accompanied by a Declaration of

Torben V. Borchert Under 37 C.F.R. 1.132 (“Borchert Declaration”). According to the Borchert Declaration, Dr. Borchert is a Director at Novozymes and an inventor of the ‘031 patent. The Amendment states that the Borchert Declaration provides evidence of unexpected results over the prior art to rebut the Examiner’s rejection of similar claims under 35 U.S.C. 103. The Borchert Declaration asserts that the experimental results presented are statistically significant and surprisingly greater than what would have been expected from the prior art cited by the Examiner. The Examiner, in a Notice of Allowability dated September 21, 2004, stated that the claims of the ‘031 patent are allowable based upon the unexpected results presented in the Borchert Declaration, which the Examiner indicated demonstrate that the claims are non-obvious over the prior art.

18. On information and belief, the ‘031 patent is unenforceable due to Novozymes’ inequitable conduct in procuring the ‘031 patent because those owing a duty of candor in prosecution of the ‘031 patent: (a) intentionally withheld from the Examiner highly relevant experimental data that were obtained prior to and during the course of the experiments reported in the Borchert Declaration; (b) intentionally withheld from the Examiner a literature reference, Machius *et al.*, J. Molec. Biol. (1995) 246: 545-559 (“Machius 1995 paper”), which was published before the earliest-effective filing date of the ‘031 patent and disclosed information that is highly relevant to the patentability of the subject matter claimed in the ‘031 patent and non-cumulative to the art cited by the Examiner; and (c) misrepresented to the PTO the significance and unexpected and/or surprising nature of alleged experimental results and the appropriateness of the design of the alleged underlying experiment reported in the Borchert

Declaration, upon which misrepresentations the Examiner relied in allowing the claims of the '031 patent.

19. Prior to conducting the alleged comparative experiments reported in the Borchert Declaration, Novozymes' scientists conducted certain "calibration work" to determine what inactivation temperature and other conditions to use in experiments comparing the claimed invention to the prior art. Upon information and belief, that "calibration work" produced experimental data that is inconsistent with the comparative results reported in the Borchert Declaration. At least Dr. Borchert and possibly others having a duty of candor to the PTO knew the results of such calibration work and knew or should have known that such results were inconsistent with the comparative results presented in the Borchert Declaration, yet he/they intentionally failed to present those results to the Examiner during prosecution of the '031 patent. On information and belief, only if the Examiner had known the results of such "calibration work" could there have been a full and fair evaluation of whether the Borchert Declaration established unexpected and/or surprising results.

20. With respect to the alleged comparative experiments that were reported in the Borchert Declaration, Dr. Borchert and/or his technician, who was working under Dr. Borchert's direction in conducting the experiments, obtained results in the very same experiment that were omitted from the Borchert Declaration. Dr. Borchert knew or should have known that such omitted results would have affected the experimental results and conclusions presented in the Borchert Declaration, yet such omitted results were intentionally withheld from the Examiner during prosecution of the '031 patent. On information and belief, only if the Examiner had

known about the omitted results could there have been a full and fair evaluation of whether the Borchert Declaration established unexpected and/or surprising results.

21. The comparative experiments reported in the Borchert Declaration purported to show that one of the claimed amylases was surprisingly and unexpectedly more thermostable than the prior art amylases. However, on information and belief, these experiments were designed with conditions that exaggerated the difference in properties between the amylase of the claims and the prior art amylases. Specifically, the experimental design utilized a lower calcium concentration than and an inactivation temperature different from that of the prior art cited by the Examiner. These conditions destabilized the prior art amylases so much that the benefits of the claimed invention were impossible to accurately evaluate. Additionally, there is no evidence that the amylases used in the comparative experiments to represent the prior art cited by the Examiner were, in fact, the same as or equivalent to the amylases of such prior art. Moreover, the comparative experiments and analysis thereof failed to accommodate the time needed to heat the amylase solutions to the inactivation temperature, thus introducing a systematic error into at least some of the data reported in the Borchert Declaration. Collectively, on information and belief, the experimental design of the Borchert Declaration yielded data from which it was improper to calculate the relative thermostability of the amylases tested and led to a vast overstatement of the allegedly improved thermostability of the claimed amylases.

22. During prosecution of the '031 patent, at least Dr. Borchert and Novozymes' in-house patent attorney, Mr. Garbell, were fully aware of the teachings of the Machius 1995 paper and knew or should have known that such paper contained teachings that were not found in the

prior art considered by the Examiner and were highly material to patentability of the claims of the '031 patent. Nevertheless, neither Dr. Borchert nor Mr. Garbell nor anyone at Novozymes disclosed the Machius 1995 paper to the Examiner during prosecution of the '031 patent. On information and belief, the Machius 1995 paper would have provided a basis for rejecting the claims that issued in the '031 patent that was stronger than the art cited by the Examiner and which no evidence of unexpected and/or surprising results could have rebutted.

23. On information and belief, on September 3, 2004, Dr. Borchert and Mr. Garbell engaged in a face-to-face interview ("Interview") with the Examiner. On information and belief, during the Interview Dr. Borchert and Mr. Garbell discussed a draft declaration with the Examiner and made, directly and through the draft declaration, statements similar to those described in paragraph 17 above, on which the Examiner relied to allow claims of the '031 patent.

24. Dr. Borchert, Mr. Garbell and Elias Lambiris, Novozymes' other patent attorney of record, each and all owed a duty of candor for prosecution of the '031 patent. On information and belief, Dr. Borchert, Mr. Garbell and Mr. Lambiris knew or should have known that the results presented in the Borchert Declaration and/or in the Interview are not actually statistically significant, that the poor experimental design precludes drawing the conclusion that the results are unexpectedly or surprisingly greater than those seen in the prior art, and that the results are not, in fact, unexpected or surprising. Dr. Borchert, Mr. Garbell and Mr. Lambiris thus misrepresented the significance and nature of the results presented in the Borchert Declaration to

the PTO and the Examiner expressly relied upon those misrepresentations in allowing the '031 patent.

25. Therefore, the '031 patent is unenforceable based on inequitable conduct in its prosecution.

FOURTH AFFIRMATIVE DEFENSE

26. The '031 patent is unenforceable due to prosecution laches.

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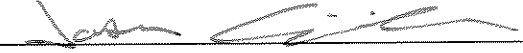
*Attorneys for Defendants
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CERTIFICATE OF SERVICE

I, Jason A. Cincilla, hereby certify that on the 9th day of February, 2006, a copy of Enzyme Development Corporation's Answer And Affirmative Defenses was served by electronic filing upon the following counsel of record:

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